

REMARKS

By way of the present amendment, claims 31, 33-38, 75-102 are pending. Claims 31, 36, 75-76, 84-85, 93 and 94 have been amended without prejudice or disclaimer. Claims 99-102 have been newly added. Support for the claim amendments can be found throughout the specification and the claims as originally filed, see, for example, Specification at page 18, line 12 - page 21, line 29; page 40, line 1 - page 41, line 3; page 42, line 19 - page 43, line 3; page 44, lines 13 - 24; page 65, line 1 - page 68, line 21; and page 72, line 6 - page 79, line 14. No new matter has been added by way of the present amendment.

I. Claim Objections

Claims 95-98 stand objected to as allegedly failing to further limit the subject matter of a previous claim. Office Action dated January 25, 2007 ("Final Office Action") at page 2. In objecting to claims 95-98, the Office asserts that an intron is "generally known in the art to be a full-length intron unless specified otherwise in the specification or the parent claim." *Id.* The Office goes on to assert that there is "no guidance to indicate that the recitation of 'a FAD2 intron' would also encompass fragments of the intron," and claims 95-98 actually broaden the subject matter of the parent claims.

While Applicants disagree, in order to facilitate prosecution, Applicants have amended claims 75-76 and 84-85 to recite a fragment of a FAD2 intron. As such, Applicants respectfully submit that claims 95-98 do not broaden the subject matter of the parent claims.

For at least the above reasons, Applicants respectfully request that the Office withdraws this objection.

II. Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 31, 33-38, and 75-94 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabling one of skill in the art to make and/or use the invention. In support of this rejection, the Office asserts that the specification, "while being enabling for the suppression of soybean FAD2 and FATB with expression of soybean FAD2 and FATB DNA sequences and the increase of expression of soybean delta-9 desaturase with the expression of exogenous soybean

delta-9 desaturase, does not reasonably provide enablement for the above described expression alterations with any DNA sequences.” Final Office Action at page 3.

Applicants respectfully disagree with the Office’s 35 U.S.C. § 112, first paragraph, enablement rejections. However, solely in order to facilitate prosecution, Applicants have amended claims 31, 36, 93 and 94 without prejudice or disclaimer. As such, Applicants respectfully assert that the claim objections are rendered moot.

The Office has again misapplied Singh *et al.* (2005 Current Opinion in Plant Biology 8:197-203). It is a review of “metabolic engineering of *new* fatty acids in plants.” Singh *et al.* at Title. The claims do not recite any fatty acids not naturally present in soybean seeds. Singh *et al.* is directed at least in part to fatty acids “normally obtained from marine sources such as microalgae and fish” and as “unusual fatty acids.” Singh *et al.* at page 197, first full paragraph and at page 200, last full paragraph. “The synthesis of LC-PUFA in higher plants therefore requires the introduction of genes that encode all of the biosynthetic enzymes required to convert either [linoleic acid or α -linolenic acid into LC-PUFA]” *Id.* at page 197, second column, last paragraph. Since Applicants’ claims are not directed to the creation of LC-PUFA or any other “new” fatty acid, Singh *et al.* is not relevant.

Applicants thank the Office for indicating that the Specification is enabling for the suppression of soybean FAD2 and FATB with expression of soybean FAD2 and FATB DNA sequences and the increase of expression of soybean delta-9 desaturase with the expression of exogenous soybean delta-9 desaturase. *Id.* Indeed, the Specification provides numerous FAD2 and FATB suppression constructs; see, for example, Specification at page 42, line 19 - page 43, line 3; page 44, lines 13 - 24; page 65, line 1 - page 68, line 21; page 72, line 6 - page 79, line 14. The Specification also provides for numerous combination constructs, see, for example, Specification at page 40, line 1 - page 45, line 17; Example 7 and Tables 7-8. Given this, Applicants respectfully submit that the claimed invention could be practiced by one of ordinary skill in the art with no undue experimentation.

For at least the above reasons, Applicants respectfully request that the Office withdraws this rejection.

III. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 31, 33-38, and 75-98 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time of filing. Final Office Action at page 5. In rejecting the claims, the Office alleges that the claimed invention is drawn to the suppression of FAD2 and FATB with any DNA sequence from any source as well as the increase of delta-9 desaturase with the expression of any DNA sequence from any source. Final Office Action at page 5.

Applicants respectfully disagree with the Examiner's 35 U.S.C. § 112, first paragraph, written description rejections. However, solely in order to facilitate prosecution, Applicants have amended claims 31, 36, 93 and 94 without prejudice or disclaimer. As such, Applicants respectfully assert that the claim objections are rendered moot.

For at least the above reasons, Applicants respectfully request that the Office withdraws this rejection.

IV. Rejection under 35 U.S.C. § 112, First Paragraph, New Matter

Claims 95-98 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time of filing. Final Office Action at page 6. In rejecting claims 95-98, the Office alleges that there is no support in the specification for the phrase "a fragment of a FAD2 intron." Applicants disagree.

The specification is replete with support for the phrase "a fragment of a FAD2 intron," see, for example, Specification at page 13, line 16 - page 14, line 2; page 14, lines 24-26; page 19, lines 3-4; and page 67, lines 21-22. Given this, Applicants respectfully submit that claims 95-98 were improperly rejected under 35 U.S.C. § 112, First Paragraph.

For at least the above reasons, Applicants respectfully request that the Office withdraws this rejection.

V. Rejection under 35 U.S.C. § 103

Claims 31, 33-38, 75, 78-84, and 87-94 stand rejected under 35 U.S.C. § 103 as allegedly being obvious over Buhr *et al.* (2002 The Plant Journal 30:155-163) in view of Thompson *et al.* (U.S. Patent No. 5,723,595). In rejecting the claims, the Office has asserted that the suppression of FAT2-1 and FATB and the expression of delta-9 desaturase was known in the prior art and that Thompson *et al.* provides motivation for combining oil content altering constructs. Final Office Action at page 7.

Applicants respectfully disagree with the Office's rejections under 35 U.S.C. § 103. However, solely in order to facilitate prosecution, Applicants have amended claims 31, 36, 93 and 94 without prejudice or disclaimer. As such, Applicants respectfully assert that the claim objections are rendered moot.

Applicants thank the Office for acknowledging that that claims 76-77 and 85-86 are free of the art and that the prior art does not teach or reasonably suggest a DNA construct comprising a FATB UTR. Final Office Action at Page 8. Indeed, neither Buhr *et al.* nor Thompson *et al.* teach or fairly suggest a DNA construct comprising a FATB UTR. Moreover, neither Buhr *et al.* nor Thompson *et al.* teach or fairly suggest a method of altering oil compositions comprising a transforming a soybean plant with a first set of DNA sequences comprising a sequence from soybean FAD2 and a sequence from soybean FATB, and a second set of sequences capable of increasing endogenous expression of at least a delta-9 desaturase gene. As such, Applicants respectfully submit that the claimed invention is not obvious over Buhr *et al.* in view of Thompson *et al.*.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. There must also be a reasonable expectation of success. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully assert that the Office has failed to establish a *prima facie* case of obviousness because the Office has not provided an adequate explanation of the suggestion or motivation to combine the teachings of Buhr *et al.* and Thompson *et al.* The Office alleges that

one of ordinary skill in the art would have been motivated to modify the composition discussed by Buhr *et al.* with the plant desaturase enzyme discussed by Thompson *et al.* Applicants respectfully disagree.

Whatever else Thompson *et al.* describes, Thompson *et al.* provides no suggestion or motivation to modify Buhr *et al.* by adding a DNA sequence that is capable, when expressed in a host cell, of increasing the expression of at least a delta-9 desaturase gene. At best, Thompson *et al.* generally discusses edible oil sources, but provides no specific motivation for increasing the expression of at least a delta-9 desaturase gene in a composition that is capable of suppressing endogenous expression of at least a soybean FAD2 gene and a soybean FATB gene. Moreover, Buhr *et al.* actually teach away from modifying plant seeds that down-regulate both FATB and FAD2 by increasing the expression of at least a delta-9 desaturase gene. As described in Buhr *et al.*, down-regulation of FATB would result in decreased levels of saturated fatty acids, such as palmitate and stearate, whereas down-regulation of FAD2-1 results in elevated levels of oleate and a reduction of polyunsaturated fatty acids. Buhr *et al.* at page 156. Because, as described by Buhr *et al.*, down-regulation of FATB would result in decreased levels of saturated fatty acids, one of ordinary skill in the art, given both Buhr *et al.* and Thompson *et al.*, would not have the requisite motivation to further lower the saturated fatty acids content by increasing the expression of at least a delta-9 desaturase gene. That is, there is no indication in either Buhr *et al.* or Thompson *et al.* that there is any sort of advantage or desirability of increasing the expression of delta-9 desaturase gene in a seed that already has decreased levels of saturated fatty acids from the down-regulation of FATB. Additionally, neither Buhr *et al.* nor Thompson *et al.* provide motivation for increasing the expression of at least a delta-9 desaturase gene in a seed capable of down-regulation of FAD2-1.

“The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing

chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.)" MPEP § 2143.01. The motivation suggested by the Office, that "various different oil compositions are desired," does not suggest the desirability of the claimed invention. Applicant therefore respectfully disagrees with the Office's assertion that one of skill in the art would have been motivated to combine the teachings of Buhr *et al.* and Thompson *et al.*

Applicants also respectfully assert that the Office has failed to establish a *prima facie* case of obviousness because there would have been no reasonable expectation of success, at the time the invention was made, in combining the teachings of Buhr *et al.* and Thompson *et al.* Applicants respectfully point out that there is no reasonable expectation in either Buhr *et al.* or Thompson *et al.* that modifying the seeds of Buhr *et al.* by increasing the expression of at least a delta-9 desaturase gene would be successful. For example, it would not have been expected that saturated fatty acids could be reduced further with the addition of a delta-9 desaturase to the invention of Buhr *et al.*. One of skill in the art would therefore have no reasonable expectation of success that modifying the seeds of Buhr *et al.* by adding the construct of Thompson *et al.* would function sufficiently well in plants to further alter fatty acid levels. For the foregoing reasons, Applicant therefore respectfully asserts that the Office has failed to establish a *prima facie* case of obviousness for Buhr *et al.* in view of Thompson *et al.*

In conclusion, the Office has failed to meet even one of the requirements to establish a *prima facie* case of obviousness.

In light of these remarks, Applicant respectfully requests withdrawal of this rejection of claims 31, 33-38, 75, 78-84, and 87-94 under 35 U.S.C. § 103 for purportedly being unpatentable over Buhr *et al.* in view of Thompson *et al.*

VI. Double Patenting Rejection

Claims 31 and 33-38 stand provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 31 and 33-38 of co-pending U.S. Application Serial No. 10/508,401.

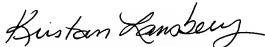
Applicants respectfully disagree with the Examiner's Double Patenting rejections over claims 31 and 33-38 of co-pending U.S. Application Serial No. 10/508,401. However, solely in order to facilitate prosecution, Applicants have amended claims 31, 36, 93 and 94 without prejudice or disclaimer. As such, Applicants respectfully assert that the claim objections are rendered moot.

For at least the above reasons, Applicants respectfully request that the Office withdraws this rejection.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objection and rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,



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